

### **REMARKS/ARGUMENTS**

Reconsideration of the present application, as amended, is respectfully requested.

Claims 24-45 are pending. Claims 24, 27, 39 and 41 have been amended to more clearly define the invention described therein. No new matter has been added.

#### **THE CLAIMED INVENTION IS NOVEL UNDER 35 U.S.C. 102(e)**

At item 6 of the Office Action, the Examiner has rejected claims 24-34, 35-40 and 43-45 under 35 U.S.C. 102(e) as allegedly anticipated by Biedermann et al. (U.S. 5,980,921) (hereinafter "Biedermann"). The Examiner takes the position that Biedermann describes a topical composition "formulated as a cleansing composition in the form of bath gels, liquid, shampoos, hair tonic, pastes and mousses..." that also can comprise a "film forming polymer that is not tacky..."

Applicants respectfully disagree. In order to anticipate a claimed invention, a reference must describe each and every element of the invention as claimed. The following table compares the elements of pending claim 24 with the description of the Beiderman references.

Claim 24: A delivery device comprising	Biedermann: Not a device, but an emulsion.
water-dissolvable, non-tacky, <i>dry</i> uniform layer,	No dry uniform layer. "Such compositions contain a film forming polymer/plasticizing solvent in the <i>aqueous</i> (internal) phase of the emulsion." (Col. 8, lines 56-67).
wherein the uniform layer comprises a water-dissolvable filmogenic polymer	No <i>dry</i> uniform layer is described
and an effective dose of an active substance	Active substances are recited (Col. 4, lines 20-28).
wherein the uniform layer is dissolvable upon application onto a wetted skin tissue or mucosal epithelial tissue of a subject, and wherein the delivery device is suitable for application to skin or mucosal epithelial tissue of a subject.	No description of a film that is "dissolvable upon application." and that is "suitable for application..."

As can be readily appreciated by comparing the above table, claim 24 is directed to a "delivery device" that includes a "water-dissolvable, non-tacky, dry uniform layer..." that is "suitable for application to skin or mucosal epithelial tissue of a subject" in its dry state. It is respectfully submitted that Biedermann fails to describe or suggest any such delivery device.

Instead, Biedermann describes an aqueous composition for application to skin. The phrase, "wherein the uniform layer is dissolvable..." is respectfully urged to make it clear that the claimed device is dry before contact with skin. The Biedermann composition is clearly an emulsion before contact with skin. While the Biedermann composition may well form a dry film after contact with skin, it is urged such a film is not a "device" that suitable for applicable to the skin, as required by claim 24. Biedermann, at Col. 8, lines 62-66, describes their resulting film as follows.

Of course, the polymer must be capable of forming a thin elastomeric film that physically adheres or interacts with the skin. The polymer film, when formed must also be water removable, that is easily removable with water and soap.

However, nowhere is there any description or suggestion that the film so produced can be used in its dry form as a device that can be "applicable" to skin. In fact, there is no description or suggestion that the film that results when the Biedermann composition (emulsion) is applied to skin, and allowed to dry, can be thereafter separated from the skin, and employed as a device. This is made clear by the requirement that the Biedermann polymer film be "easily removable with water and soap."

In addition, it is submitted that Biedermann fails to describe or suggest the methods of claims 43-45, since those claims require that the applied device is dry before application to the skin or mucosal surface the recited process.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### **THE CLAIMED INVENTION IS NONOBVIOUS UNDER 35 U.S.C. 103(a)**

At item 9 of the Office Action, claims 35 and 42 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Biedermann, as discussed above. The Examiner concedes that "Biedermann does not disclose a single layer device," but asserts that, there is not demonstration that at least 75% of the film-forming polymer provides unusual/unexpected results to the composition."

Applicants respectfully disagree. In order to sustain a *prima facie* obviousness rejection under 35 U.S.C. 103(a), the Patent Office has the burden of coming forward with a combination of references, or with a reference and other information from the state of the art, from prior to the filing date (priority date) of the subject patent application, showing all of the elements of the

invention as claimed, and a suggestion or reason why the artisan would have made the alleged combination, that is found in the references or state of the art.

It is respectfully submitted that the instant rejection simply fails to meet the requirements of the law. The shortcomings of Biedermann as an anticipatory reference are discussed above. Since no rejection under 35 U.S.C. 103(a) has been asserted against independent claim 24, the Examiner has apparently conceded that independent claim 24 is free of the art of record under 35 U.S.C. 103(a). In addition, the law is clear that, if an independent claim is free of the art of record, then all claims depending from the independent claim are also free of the art of record. The Examiner is simply not free to point to some specific element of a dependent claim and burden applicants with a requirement to show unexpected results.

Further, the Examiner has not made the required showing that any element(s) missing from Biedermann as a reference, for example, the dryness of the claimed device before application, are provided by another reference and why such other reference would have been considered by the ordinary artisan. If the Examiner is basing her rejection under 35 U.S.C. 103(a) on personal knowledge, she is respectfully requested to make such personal knowledge of record in the form of a Declaration Under 37 C.F.R. 1.132.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### **PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CO-OWNED U.S. APPL. SERIAL NO. 09/340,338**

At item 12 of the Office Action, the Examiner has provisionally rejected claims 24, 25, 30-32 and 35 over pending claims 67 and 71-75 of co-owned U.S. Appl. Ser. No. 09/340,338.

Applicants enclose herewith a Terminal Disclaimer, together with the required Petition Fee, terminally disclaiming the term of the instant patent, once granted, over the term of Ser. No. 09/340,338, once granted.

This ground of rejection is now obviated.

#### **CONCLUSION**

This response is being timely filed. No fee is believed to be due. If, on the other hand, it is determined that any fees are due or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R.

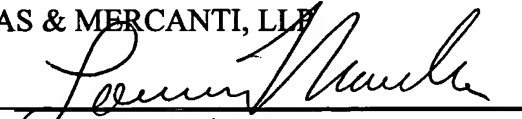
1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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